K091786

JUN 18 2010

PULSION
Medical Systems

Section 3.0

510(k) Summary or Statement

Preparation Date:	May 24, 2010
Applicant/Sponsor:	Pulsion Medical Systems AG 20 Joseph-Wild-Strasse Munich, Germany 81829
Contact Person:	Christoph Manegold, Director Research and Development Phone: 214-557-8730 Fax: +49 89 459 914 18
Trade name:	PULSION PiCCO-2 with Optional CeVOX™ Accessories
Common Name:	• Computer, Diagnositic, Pre-programmed
Classification Name:	• Single-function, preprogrammed diagnostic computer (21 CFR 870.1435)
Device Product Code:	• DXG

Legally Marketed Devices to Which Substantial Equivalence Is Claimed:

PULSION PICCO-2, MODEL 8500	K072735
VIGILEO ARTERIAL PRESSURE CARDIAC OUTPUT/OXIMETRY MONITOR	K062134
EDWARDS LIFESCIENCES LLC PRESEP AND PEDIASAT OXIMETRY CATHETERS	K053609

Device Description:

The PULSION PiCCO-2 is a microprocessor-based instrument intended for the determination and monitoring of cardiopulmonary and circulatory variables. When the optional CeVOX™ optical module and probe are connected to the PiCCO-2, the monitor measures oxygen saturation in adults or pediatrics. In addition, the PiCCO-2 measures heart rate, systolic, and diastolic and derives mean arterial pressure. Analysis of thermodilution curve in terms of mean transit time and downslope time is used for determination of intravascular and extravascular fluid volumes. If a patient's weight and height are entered, the PiCCO-2 presents the derived parameters indexed to body surface area.

Indications for Use:

The PULSION PiCCO-2 is intended for determination and monitoring of cardiopulmonary and circulatory variables. With the optional CeVOX™ oximetry module connected to an oximetry probe, the PiCCO-2 measures oxygen saturation to assess oxygen delivery and consumption in adults and pediatrics. Cardiac output is determined both continuously through pulse contour analysis and intermittently through thermodilution technique. In addition, the PiCCO-2 measures heart rate, systolic, and diastolic and derives mean arterial and central venous pressure. Analysis of thermodilution curve in terms of mean transit time and downslope time is used for the determination of intravascular and extravascular fluid volumes. If a patient's weight and height are entered, the PiCCO-2 monitor presents the derived parameters indexed to body surface area.

Comparative Analysis:

The PULSION PiCCO-2 with optional CeVOX™ accessories has been demonstrated to be as safe and effective as the predicate devices for its intended use.

Functional/SafetyTesting:

The PULSION PiCCO-2 with optional CeVOX™ accessories has successfully undergone functional testing demonstrating equivalence to the predicate devices. The subject and predicate devices are similar in design, principle of operation, materials of construction, intended use, labeling and manufacturing processes. In vivo non-clinical testing, sterilization validation and biocompatibility testing was conducted. Results of all non-clinical testing met associated acceptance criteria and did not raise new issues of safety and/or effectiveness.

Conclusion:

The PULSION PiCCO-2 with optional CeVOX™ accessories are substantially equivalent to the predicate devices.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room –WO66-G609
Silver Spring, MD 20993-0002

JUN 18 2010

Pulsion Medical Systems Ag
C/O Dr. Jamie Sulley, President
Triangulum Consulting Services, Inc.
7220 Sparhawk Rd.
Wake Forest, North Carolina 27587

Re: K091786
Trade/Device Name: PULSION PiCCO-2 with Optional CeVOX Accessories
Regulation Number: 21 CFR 870.1435
Regulation Name: Single-Function Pre-Programmed Diagnostic Computer
Regulatory Class: Class II
Product Code: DXG
Dated: May 15, 2010
Received: May 25, 2010

Dear Dr. Sulley:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21

CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

for Bram D. Zuckerman, M.D.
Director
Division of Cardiovascular Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

PULSION
Medical Systems

Section 1.0

Indications for Use Statement

510(k) Number (If known): K091786

Device Name: Pulsion PiCCO-2 with Optional CeVOX™ Accessories

Indications for Use:

The PULSION PICCO-2 is intended for determination and monitoring of cardiopulmonary and circulatory variables. With the optional CeVOX™ oximetry module connected to a compatible oximetry probe, the PiCCO-2 measures oxygen saturation to assess oxygen delivery and consumption in adults and pediatrics. Cardiac output is determined both continuously through pulse contour analysis and intermittently through thermodilution technique. In addition, the PiCCO-2 measures heart rate, systolic, and diastolic and derives mean arterial and central venous pressure. Analysis of thermodilution curve in terms of mean transit time and downslope time is used for the determination of intravascular and extravascular fluid volumes. If a patient's weight and height are entered, the PiCCO-2 monitor presents the derived parameters indexed to body surface area.

The following tabular shows the parameters measured by the $PiCCO_2$ patient monitor and their specifications:

Label	Unit	Lower limit	Upper limit	Accuracy*	Remark
CO	l/min	0.25	25	Coefficient of variation ≤ 2%	Valid over full range
GEDV	ml	40	4800	Coefficient of variation ≤ 3%	Valid over full range
ITBV	ml	50	6000	Coefficient of variation ≤ 3%	Valid over full range
EVLW	ml	10	5000	Coefficient of variation ≤ 6%	Valid over full range
PCCO	l/min	0.25	25	Coefficient of variation ≤ 2%	Valid over full range
SV	ml	1	250	Coefficient of variation ≤ 2%	Valid over full range
SO_2	%	1	99	±2%	valid from 40 – 99%
SvO_2	%	1	99	±2%	valid from 40 – 99%
$ScvO_2$	%	1	99	±2%	valid from 40 – 99%

* Statistical evaluation based on random examination of actual production output

Prescription Use __X__ AND/OR Over-The-Counter Use _____
(Part 21 CFR 801 Subpart D) (21 CFR 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Cardiovascular Devices

510(k) Number K091786